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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/855,158

05/14/2001

Lars Eyde Theill

A-686A

8931

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7590

03/14/2008

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EXAMINER

CANELLA, KAREN A

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

03/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/855,158	Applicant(s) THEILL ET AL.	
	Examiner Karen A. Canella	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 13 and 17 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 13, 17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 14-16 have been canceled. Claims 13 and 17 have been amended and are under consideration.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites “one of P¹ and P² is a specific binding partner for AGP-3 and the other is a specific binding partner for APRIL”. This is vague and indefinite in the event that the composition has no P², such as when X¹ or X² is selected as (L¹)_c-P¹.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The rejection of claim 13 under 35 U.S.C. 102(a) as being anticipated by Gross et al (Nature, April 27, 2000, Vol. 404, pp. 995-999) is maintained for reasons of record. Amended claim 17 is also rejected for the same reasons of record.

Claim 13 is drawn in part to compositions comprising an Fc domain linked to the consensus region of TACI (SEQ ID NO:16) or the consensus region of BCMA (SEQ ID NO:7), but not the entirety of the extracellular region of TACI (SEQ ID NO:15) or the entirety of the extracellular region of BCMA (SEQ ID NO:6). It is noted that the indices of a, b and c can be either one or zero, with the exception that either a or b must be one, therefore the claims encompass structures wherein a=1, b=zero and c=zero. With c=zero "P" is directly attached to F' without a linker L¹. Thus, the Fc domain is attached directly to a portion of TACI or BCMA including SEQ ID NO:16 or SEQ ID NO:7, but excluding SEQ ID NO:15 or SEQ ID NO:6. Claim 13 has the further requirement that the "P" region is a specific binding partner for AGP-3 or APRIL. Claim 17 embodies the method of claim 13 wherein F' is an Fc domain.

Gross et al disclose an artificial construct comprising residues 1-154 of human TACI fused to a human Fc domain and an artificial construct comprising residues 1-48 of human BCMA fused to a human Fc domain (page 998, second column, lines 6-10 under the heading of "Recombinant Proteins"). The constructs meet the limitation of not comprising SEQ ID NO:15 or SEQ ID NO:6 because residues 1-154 of TACI are less than residues 1-166 of SEQ ID NO:15, and residues 1-48 of BCMA are less than residues 1-51 of SEQ ID NO:6. The constructs of Gross et al fulfill the limitation of being a specific binding partner for APRIL or AGP-3 because the artificial proteins of Gross et al comprise the required binding sequences for binding to APRIL or AGP-3.

The rejection of claims 13 under 35 U.S.C. 102(e) as being anticipated by Shu (U.S. 6,475,987) is maintained for reasons of record. Claim 17 is also rejected for the same reasons of record.

Shu discloses human BCMA (SEQ ID NO:11) as the Tall-1 receptor (column 23, lines 37-50). Shu discloses fusions of the entire extracellular domain of BSMA to a FLAG-tag and an Fc domain (column 46, lines 15-19 and lines 65). Shu discloses that Tall-1 receptor includes

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fusion protein and homologues (column 22, lines 64-67 and that homologues include Tall-1 receptors in which a few amino acids have been deleted, including truncated version of the protein (column 23, lines 11-16). Thus, the disclosure of FLAG-sBCMA-Fc encompasses the instant invention because Shu specifically discloses the scope of the invention as including a Tall-1 receptor with a few amino acids have been deleted and therefore includes sBCMA that is less than the entire extracellular region do to deletion of a few amino acids from either the carboxyl terminus or the amino terminus or both.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/

Primary Examiner, Art Unit 1643